EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 212-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL WAVE 8 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

*****VOLUME II*****

CONTINUED DEPOSITION OF OZ HARMANLI, M.D.

Taken pursuant to the Federal Rules of Civil Procedure, at the offices of New Haven Legal Center, LLC, 900 Chapel Street, New Haven, Connecticut, before Vicki S. McManus, a Licensed Shorthand Reporter and a Notary Public in and for the State of Connecticut, Shorthand Reporter License No. 00152, on Wednesday, October 3, 2018, at 5:26 p.m.

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STIPULATIONS

IT IS HEREBY STIPULATED AND AGREED by and between counsel for the respective parties hereto that all technicalities as to proof of the official character before whom the deposition is to be taken are waived.

IT IS FURTHER STIPULATED AND AGREED by and between counsel for the respective parties hereto that the reading and signing of the deposition by the deponent are required.

IT IS FURTHER STIPULATED AND AGREED by and between counsel for the respective parties hereto that all objections, except as to form, are reserved to the time of trial.

* * * * *

OZ HARMANLI, M.D.,
called as a witness, having been previously duly sworn, was examined and continued his testimony as follows:

DIRECT EXAMINATION CONTINUED

BY MR. FAES:

Q Doctor, we are back on the record after a short break. Are you ready to proceed?

A Yes.

Q Earlier, before we took a break, we were talking about just erosion rates for TVT and TVT-O devices, and it seemed like you were getting a little fired up. Is that accurate?

MR. ROSENBLATT: Object to form.

A I feel that it's unfair when good data, which we have on TVT, is bypassed in favor of really bad quality, outlier studies.

BY MR. FAES:

Q Would you consider yourself somewhat of an advocate for the midurethral sling?

A I am an advocate of patients. I really am a women's health advocate. I consider myself that way.

Q Do you consider yourself an advocate for the midurethral sling?

MR. ROSENBLATT: Object to form.

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A I have been in this area for, right now, over 20 years. I've seen the most effective and, at the same time, the lowest risk thing I have done on my patients to get the best results have been through midurethral slings.

Because of that, I support midurethral slings. I can't imagine what I would do without midurethral slings, being a urogynecologist.

BY MR. FAES:

Q Do you think that makes it difficult for you to be fully objective, the fact that you can't imagine what you'd do without the sling?

A That's not exactly how I would interpret that.

What I'm saying is: The alternatives to midurethral slings are so much more unfavorable, that for me to offer those other procedures to the patients, because of this unfair attack on midurethral slings for really not scientifically proven complications, is unfair.

So someone has to be there for support or defend women's health causes.

Q And you feel that's part of your job, is to advocate and defend for women's health products, right?

A Not women's health products. I'm talking about women's health issues. I am -- that's my job.

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Q Doctor, on page 15 of your report -- actually it starts, say, on the previous page, on 14. It states "A survey conducted by Faber 2017 helps demonstrate the stark contrast of how surgeons don't read or rely on the IFU in clinical practice compared to the importance that is placed in the IFU in litigation."

Do you see that?

A Yes.

Q Is that an opinion that you intend to offer in this case, is that surgeons don't read or rely on the IFU in clinical practice?

A Surgeons, and the educators of surgeons as what -- myself being one of them, we really just teach general precautions, concepts, and risks and complications about the procedures.

So IFU may touch bases with some of them and maybe it misses some others.

That's not my job, to really make sure that people read IFUs. My job is to make sure the people I train, the patients I counsel on this thing, the risks and complications, as long as they are well described, it's upon me, incumbent upon me to discuss that and teach that. That's what I really pay attention to the most.

Q I appreciate and that's helpful. My question's

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actually a little different.

My question was: Do you intend to offer an opinion in this case that surgeons don't read and rely on the IFU for the TVT and TVT-O in clinical practice?

A For practical purposes, as this study indicated, they are less commonly looked than what litigation claims basically.

Q But you'd agree with me that this particular study, if you want to call it that, or survey, that was published by Faber, actually supports that the majority of urologists and pelvic floor surgeons have actually reviewed the IFU for a pelvic mesh product at least once, right?

A Correct. They do look. That makes sense. Because we are supposed to read them.

But do we actually read them? That's the question. And how often do we read them? So that's why I think this study helps us, enlighten us about that.

Q Right. This study actually reflects that indeed the majority of surgeons who utilize these products have reviewed it at least once, right?

A Correct. But that means that many times they didn't.

Q Do you think it's a reasonable thing for a

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physician to do to review the Instructions For Use for a pelvic mesh device before using it for the first time?

A It certainly is a good information, piece of information, to acquire before using it, because FDA spends so much time helping company design that. So it needs to be looked at, for sure. But it cannot be the only piece of information that makes the surgeons go to the OR or counsel the patients based on.

Q Well, and you actually train physicians on pelvic mesh products all the time, right?

A Correct.

Q Now, what Ethicon products do you currently train physicians on?

A Currently I use TVT.

Q Do you also train physicians on the Boston Scientific Halo?

A I use the Obtryx for the transobturator approach.

Q Sorry, I said that wrong.

So you also currently train physicians on the Obtryx too, right?

A That is correct.

Q Any other pelvic devices, pelvic mesh devices that you are currently training physicians on?

A I use Centacopal [ph] XT mesh. And my current

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product of choice and available to me is also -- is Restorelle from Coloplast. And then occasionally I still do transvaginal mesh placement for prolapse, and that would be using a Restorelle mesh. Sometimes I just cut it and shape it, because, unfortunately, that is also becoming harder to offer to the patients.

Q But those are the -- are you also training on the Restorelle mesh or not?

A Rest -- transvaginal Restorelle mesh? I am not necessarily doing enough to train my fellows on it.

Q Okay. So when you train physicians on the TVT and TVT-O, do you go over the contents of the IFU with them?

A I don't take IFU out, if that's what you're asking. Instead -- and teaching in the OR is not like a lecture, clearly.

So the way in medicine we teach is at every step of patient care and some in a formal lecture form. But there's constant teaching, sometimes coming from direct patient care, sometimes indirect patient care, that we go over risks, complications, alternatives.

Sometimes they're in the form of a conference and that we have a meeting every week, we call it pre-op conference. That's a great teaching session. When we go over procedures, sometimes we pick the right

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procedure among ourselves, like in a consensus when a decision cannot be made.

All of that, typically IFU doesn't come out within -- during discussion. Because we already know as part of what we are going to be discussing. And if an IFU doesn't have certain information, do we care? We already cover it, because we do pelvic surgery, which is a risky business.

Q Right. But during these -- in addition to hands-on training, you also provide lectures or didactic training, right?

A Correct.

Q During those lectures or didactic training, there is materials many times that are distributed, whether it be PowerPoints or resource monographs, correct?

A Correct. If it is myself leading a lecture, without any association with any company, IFU never comes out. I can tell you that.

And I don't think in any lecture I've seen, people refer -- put pictures of IFU and make a slide of those adverse events and precautions or warnings ever in the slides.

You'll see them when it's a company-sponsored teaching session, that actually they are required to use those rather than anything else actually. So...

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Q So you'd agree with me that at least at a company-sponsored training event for a TVT or TVT-O, maybe not the actual IFU itself will be looked at but materials from the IFU will be in the training material, right?

A They are supposed to include their IFUs in their training, and I'm sure they expand upon it.

Q So further on on the same page, it states that "The risks of pelvic floor surgery are commonly known to surgeons regardless of what is contained in the IFU."

Do you see that?

A Correct.

Q Is that an opinion you intend to offer in this case to a reasonable degree of medical certainty?

A Correct.

Q I note that you state it as "The risks of pelvic floor surgery are commonly known to surgeons regardless of what is contained in the IFU," but you don't state that the risks of the TVT device are commonly known to surgeons regardless of what is contained in the IFU.

Is there a reason for that?

A So slings, midurethral slings, TVT, TVT-O, or similar procedures, are pelvic floor surgeries. And we understand that pelvic floor surgery comes with risks

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and potential complications. So regardless.

So whenever we are discussing pelvic floor surgery, with or without mesh placement, we go over those things. So -- and you don't need to look at the IFU, what I'm saying, in addition to that. You are already covering all the bases.

So IFU is not necessarily on a day-to-day basis guidance for us. But it's something FDA asks companies to do through -- for the regulatory process. That's how I see it.

Q So if I state it as "The risks of the TVT and TVT-O are commonly known to surgeons regardless of what is contained in the IFU," do you agree with that?

A So as in any pelvic surgery, the risks of TVT/TVT-O are commonly known to surgeons regardless. I would agree with that statement.

Q So that's a -- and is that an opinion you intend to offer to a reasonable degree of medical certainty in this case?

A Correct.

Q And is it your opinion that the risks of the TVT and TVT-O are commonly known to surgeons now or at any time during when the TVT and TVT-O were available in the United States?

A So from day one, we understood these procedures

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also introduced foreign material to the body, so -- but foreign material has been introduced to human body decades ago.

So any surgeon understands that, when surgery involves implantation of synthetic or nonautologous material, there are also things associated with that. We start teaching them from the first day of medical school.

You should understand immunology, you would understand some of those things too.

Q Have you ever done any kind of survey or formal analysis or study of what risks pelvic floor surgeons knew about the TVT and TVT-O at any given time?

A I haven't done a study like that.

Q So would you agree with me that your opinion that the risks of the TVT and TVT-O are commonly known to surgeons isn't based on any formal analysis?

MR. ROSENBLATT: Object to form.

A I would say that it's based on just inherent nature of pelvic surgery, that the risks of any pelvic surgery is well known to everybody else. That includes application of slings in the form of TVT or TVT-O.

BY MR. FAES:

Q Right. And, again, you are answering with pelvic floor surgery, and I'm asking specifically about the

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risks of the TVT and TVT-O, not general pelvic floor surgery.

So have you done, like, for example, an analysis -- any kind of analysis or study to see what percentage of pelvic floor surgeons knew that chronic pain could result from the TVT when the TVT was launched in, you know, 2000 in the United States?

MR. ROSENBLATT: Object to form.

A So they would -- chronic pain or discomfort at the surgical site, for any reason, we already know that our procedures prior to slings were doing that. So it was always in our teachings.

BY MR. FAES:

Q But my question is: Did anybody -- have you ever done any kind of study to determine what percentage of physicians knew that chronic pain could result specifically from the TVT mesh at the time of launch in 2000?

A I answered that question already as no.

Q Okay. What about in say 2009, same answer?

MR. ROSENBLATT: Object to form.

A So clearly TVT was a brand-new procedure when it was first launched here. Like any procedure, it was done more and more every year, and then we started seeing problems from that procedure the same way as we

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saw problems coming from the alternative procedures.

We were not surprised that TVT or TVT-O in 2009 were causing some problem with pain at the surgical site or surrounding, because we already knew that was happening decades ago from our native tissue repairs.

BY MR. FAES:

Q Right. But have you ever -- you never did -- strike that. You've already answered it.

So I mean same question with regard to the risk of pain with intercourse from the mesh which may not resolve: Have you ever done any kind of analysis or study as to what percentage or number of pelvic floor surgeons knew that was a risk from the TVT mesh when the TVT was launched?

MR. ROSENBLATT: Object to form.

A So that's not required. And, in fact, there are studies which show that actually that is not true.

BY MR. FAES:

Q So you don't think that pain with intercourse, which in some patients may not resolve, is a potential adverse reaction from the TVT mesh?

A It's not necessarily related to TVT itself. Any pelvic surgery can cause dyspareunia.

Q But do you believe -- my question is: Do you believe that that's a potential adverse reaction from

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the TVT device or the TVT mesh?

A From any procedure I do in the vagina, I can cause pain.

Q Right.

A I share that with patients.

Q I'm not asking about the procedure though. I'm asking specifically about the TVT mesh.

A Just like the other procedures, TVT can cause pain too. So that was known to me already.

I'm cutting inside the vagina. I'm making an incision inside an vagina. I don't know which way it goes. It could cause infection, wound dehiscence, and all kind of things. I don't know how her body reacts to this infection.

So I can place a mesh underneath or not. This patient may have some complication which leads to pain.

Unfortunately, vagina is an instrument, is an organ, for intercourse, and if you have any sensitive area in that area from whatever you do, it can cause pain. Therefore, TVT is no different from anything else I do there.

Q Do you think it's reasonable for Ethicon and Johnson & Johnson to warn in their IFU, or Instructions For Use, that the TVT device may cause acute and/or chronic pain?

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MR. ROSENBLATT: Object to form.
A I don't think it's needed. We know for a fact -- I've done all kind of native tissue repairs for years. I cause many times more pain from procedures which did not use any foreign material, and those patients had more pain.
Just because there is a company behind a product -- obviously they are going after Ethicon here. But it's really unfair, because I have so many patients -- and the literature's full of that. like Level I evidence in the literature shows that suture material coming out from your sacrospinous ligament fixation or uterosacral ligament fixation is more and potentially more irritative than whatever's happening with your tiny sling strip.
BY MR. FAES:
Q So I understand from your answer that you don't think it's necessary to give a warning in the IFU for TVT of acute or chronic pain, but do you think it's reasonable for a device manufacturer to do that?
MR. ROSENBLATT: Object to form.
A I didn't say that.
BY MR. FAES:
Q I'm asking you: Do you think it's reasonable or unreasonable?

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A Look, if FDA is fine with the way the IFU's written as the regulatory body in this country, I'm not going to argue against it.
But do I remain within the boundaries of that, as it -- as a prudent surgeon? Obviously not. I'm going to cover all the bases, which will include discussion of acute and chronic pain with any procedure I do in the pelvis.
Q So is your only criteria for whether or not an adverse reaction needs to be warned about in the IFU, or Instructions For Use, whether or not the FDA is requiring it? Or do you --
A If they volunteer to include it in there, it's fine. That's their business. I will continue to warn my patients about acute and chronic pain as any prudent surgeons would do.
Q So you'd agree with me that it's reasonable for a manufacturer like Ethicon and Johnson & Johnson to go beyond what is legally -- the bare minimum that's legally required and put additional warnings in the Instructions For Use if they think it's relevant and helpful to physicians, right?
MR. ROSENBLATT: Object to form.
A It's up to them. I don't mind if they do either. I'll do my thing, which is already reviewing all these

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long-term risks with the patients, regardless of the fact that I'm inserting an implant or not.
BY MR. FAES:
Q What about: Do you think it's reasonable for Ethicon and Johnson & Johnson to warn about neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area, with the TVT or TVT-O device?
A If you do any kind of cutting or insertion into that area, you definitely have the risk of affecting some muscular, neurologic, maybe joint, function. That's given. There's no surgery which wouldn't do that.
So it's inherent in any surgery that all the anatomic structures in the area of surgery can be affected, including nerves and muscles.
Q So you'd agree that that's a reasonable warning for a medical manufacturer device to include in their IFU?
MR. ROSENBLATT: Object to form.
A I'm not saying that. I did not say that.
BY MR. FAES:
Q Do you think it's unreasonable?
Do you think it's reasonable or unreasonable?
MR. ROSENBLATT: Object to form.

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A It's up to them whether they want to do it or not. I wouldn't be against it.
BY MR. FAES:
Q So it's not unreasonable to include that in an IFU?
A I'm indifferent to it, because I will do my thing.
Q Do you think it's reasonable for Ethicon and Johnson & Johnson to inform doctors and patients that there's been reports of chronic severe pain following the use of the TVT or TVT-O mesh for SUI?
MR. ROSENBLATT: Object to form.
A I would say that if it is the regulatory process which requires that they make that change, then they should make that change. The rest is up to them.
If the regulatory body, which is FDA, is fine with the IFU as it is, I'm not going to go debate it. It's not my decision to make.
BY MR. FAES:
Q So, again, your opinion is: Unless the FDA requires it, it doesn't need to be in there, right?
MR. ROSENBLATT: Object to form.
A I am just saying that the regulatory function is FDA and I do my own risk/benefit discussion with the patient, in all kinds of surgeries, including mesh

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placement.
BY MR. FAES:
Q Well, I mean is that your opinion or not? Is it your opinion that if the FDA doesn't need it to be in there, that it doesn't need to be in there?
A My opinion is: They are obligated to follow the law. And FDA doesn't make it an issue, it does not have to be there.
Q Right. So you are essentially agreeing with me: Unless the FDA requires the warning to be in the IFU, you are fine with a particular warning not being in there, right?
A I just responded to your question.
Q Well, I'm not sure I understood your response. Can you answer that question yes or no?
A Because there is some question -- there are some questions which cannot be yes and no. So I'd rather answer it that way.
Q So you can't answer the question yes or no -- well, strike that.
So what standard are you applying for what warnings need to be in the IFU for the TVT and TVT-O product?
A FDA sets the standards. And I -- if I am not the decisionmaker for FDA, it's beyond me, and I'm not

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going to make any comment on that.
But I'm not going to stay within the boundaries of what FDA asks the company to include in their documents or information available to the patient or the surgeon. I will do my job. That's all I'm saying.
Q If physicians in another country, for example, Australia, tell Ethicon and Johnson & Johnson that they believe that there should be a warning in the IFU, even though there is already a warning regarding acute and or chronic pain, that there should be a warning regarding severe chronic pain following use of their mesh, do you think that Ethicon should put that in their IFU, or Instructions For Use?
MR. ROSENBLATT: Object to form. And I'll represent we are not holding him out as offering any opinions on foreign regulatory matters.
A All right. So then I'm not going to answer.
BY MR. FAES:
Q Well, I'm not asking about any foreign regulatory issues. I'm just simply asking if -- if a group of physicians -- well, let's back up.
If a group of physicians from another country goes to Ethicon, Ethicon and Johnson & Johnson and says, "Look, we think you should -- we know you're

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warning of chronic pain, but we think you should also warn that this chronic pain can also be very severe," do you think that's a reasonable warning for Ethicon to include in their Instructions For Use?
MR. ROSENBLATT: Object to form.
A So regards to what country they are from?
BY MR. FAES:
Q Right. Because the device is the same everywhere in the world, right?
A So basically the Australian physicians go to their own regulatory body.
Q I'm saying if a physician --
A They will deal with that. So I think they should communicate with their own regulatory body and that -- and Ethicon will decide whether -- what needs to be changed in the IFU.
It really does not make any difference in how a prudent physician should be doing out in practice. You have to still cover all those bases.
This is a serious procedure. It does have short-term and long-term effects. And we all are taught from day one about that, so we will do the same, regardless of whatever country regulatory body says, whatever, on these devices.
Q Were you aware that in fact the Australian

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authorities did ask Ethicon and Johnson & Johnson to make that change to their IFU, to put a warning in the IFU regarding severe chronic pain following implantation of the mesh?
A I have some vague information about some foreign changes in -- yes. But I'm not specifically aware of that request.
Q Were you aware that the TVT and TVT-O is no longer being sold in Australia?
MR. ROSENBLATT: Object to form. And --
A It is very sad for Australian women that it's not sold there. That's the comment I'm going to make on that. Seriously.
MR. ROSENBLATT: And completely lacks foundation, and it is inaccurate.
THE WITNESS: Yes.
BY MR. FAES:
Q Well, are you aware that if Ethicon put that warning in their IFU, that they could continue to sell it in Australia?
MR. ROSENBLATT: Object to form.
And, Andy, let's move beyond foreign regulatory. He's not offering opinions on foreign regulatory.
MR. FAES: I'm not asking any questions

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on foreign regulatory. I'm just asking what he's aware of in reaching his opinions.

A All I can say is that, as a women's health advocate, I'm in this business to help patients. There is only one motivation for me: that is helping my patients.

If that is the case in Australia, I'm really sad, really sorry for Australian women. They are missing out on a major improvement in their health. It's sad.

BY MR. FAES:

Q Earlier we were talking about consenting patients for the TVT and TVT-O.

When you consent your patients, do you inform them that there is a potential of severe chronic pain --

A Yes.

Q -- following the TVT and TVT-O?

A Definitely. And just as in I do for all the other procedures, which does not include any implantation.

Q So I take it since you give that warning to your patients, you believe it's a reasonable warning to give or you wouldn't do it, right?

A But how about native tissue repairs we do, who is going to -- who is going to then have an IFU for our

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native tissue procedures and have it placed in there? Right?

So why don't we create an IFU for everything else. Let's do that.

Q But my question was specifically you believe that -- you obviously believe that giving a woman a warning that there might be severe chronic pain following a TVT or TVT-O procedure is reasonable because that's something you do, correct?

A Look, I do it for anything. Anytime I cut, I say it. And whatever the indication for my incision, I say it. Every surgeon must say it. If they don't say it, then it's their problem.

Ethicon cannot put that in their mouth. You can put in hundred IFUs, make like billboards of those IFUs. Doesn't matter. Surgeon must know these things already. It's inherent to what we do.

Q Doctor, I apologize, but I have to ask the question again, because I think it's a yes or no question and I'm not getting a response to the question I'm actually asking.

So can I have the court reporter read back the last question please.

(Question read back.)

A Yes.

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Q So, Doctor, I assume that you intend to offer an opinion in this case that the TVT and TVT-O IFUs, or Instructions For Use, are adequate to warn physicians about the risks of the device, right?

A That is also wrong. That is consistent with the regulation. That's all I'm saying.

Q Okay. So you are not offering an opinion in this case that the warnings in the -- strike that.

You are not going to offer an opinion in this case that the warnings in the TVT and TVT-O IFU are adequate for physicians using the device?

A So let me phrase it this way: IFU, in my mind, is a regulatory document. It's between the company and FDA. If FDA says it's okay, it is okay by FDA, they met that criteria to be able to market, launch this product here, and the rest is up to me. That's all I'm saying.

I'm not saying it's adequate. FDA could ask them to do more. They should -- then do more. Whatever FDA regulatory process requires, they must meet that. That's IFU. That's the definition of IFU.

Regulatory process requires this stated in the IFU, the rest is mine. And I as a surgeon, I as a teacher, must teach my residents, fellows, and tell my patients that this is not it. There is a risk.

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Whatever is written on that IFU doesn't matter. That's all I'm saying.

Q Okay. Are you aware that Ethicon has actually updated its warnings for its TVT and TVT-O IFU over time?

A Correct.

Q Are you aware that one of the -- are you aware that they most recently updated it in 2015?

A Correct.

Q And you are aware that they added a number of adverse reactions to the IFU that weren't there prior to 2015 --

A Correct.

Q -- right?

And are you aware of what the additions are?

A I am. Like if you -- like I may not really verse them, but...

Q I'm going to mark Exhibit Number 12. This is a 2015 TVT IFU.

MR. FAES: Do you want one, Paulie?

MR. ROSENBLATT: Sure. Thanks.

BY MR. FAES:

Q So if you turn to the Adverse Reactions section, basically everything starting with "acute and/or chronic pain" down is all -- all information that was

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added. Is that --
A Correct.
Q -- basically correct?
Do you believe that a physician -- if a physician prior to 2015 didn't know that these things were an adverse event, potential adverse event from the TVT procedure, that they had somehow fallen below the standard of care?
A They already knew all of this. All of this is inherent to everything we do inside the vagina, period.
You don't need that in the IFU. That's what I've been saying. You don't really need it. But FDA probably asked them to expand it or they maybe were forced because of the litigation to include it.
But it doesn't change my opinion on one fact. My job is to cover all those, and I already learn it on day one of my clinical education.
Q But I guess my question is: If a doctor stated that they didn't know prior to this IFU coming out that one or more of these new adverse reactions that were added was a risk of the TVT or TVT-O device, would you fault that physician for not knowing that?
A Literally I would see as a problem of the surgeon, unfortunately. That's why it's not needed. Because that means that surgeon did not pay attention

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to one of the most important things of any type of pelvic surgery, which is risk to the surrounding organs, and some that may remain forever. You don't need a company to tell you that.
Q Do you think -- do you believe that excessive contraction or shrinkage of tissue surrounding the TVT mesh is an adverse event that can occur with the TVT?
A I do not believe that.
Q You don't?
A I do not believe contraction.
Q So you don't believe -- do you believe that excessive contraction or shrinkage of tissue surrounding pelvic mesh can't occur at all or you just believe it doesn't happen with the TVT?
A I do not believe specific to TVT that it happens. And the most important thing is, whether it happens or not, we have so much, so convincing long-term data, that I don't even care about it.
Q Do you think that excessive contraction or shrinkage of tissue surrounding the mesh can occur with any of Ethicon's Prolene mesh products?
MR. ROSENBLATT: Object to form.
A This is not the focus of any other products, so let's just say within TVT, TVT-O.

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BY MR. FAES:
Q Well, I'm just asking about Prolene products in general. Do you think that can --
A I will discuss that in another session. Maybe if there is a deposition for anything else, I will cover that. But I'm just going to stick with TVT, TVT-O information, if you don't mind.
Q So as you sit here today, you don't have any opinions as to whether or not excessive contraction or shrinkage of tissue surrounding the mesh can occur with Ethicon's Prolene mesh?
A It's irrelevant to my expert report.
Q So you don't have -- you don't intend to offer an opinion on that issue sitting here today?
A I do not intend to offer any opinion on that.
Q Do you have an opinion -- since you do not have an opinion as it to whether or not it occurs --
A That's wrong. What you just said is wrong. I have an opinion, but I'm not going to offer that opinion right now.
MR. ROSENBLATT: I believe what he's saying is he has an opinion for TVT/TVT-O, but if you are asking him about other meshes, he did not include other meshes in his report.

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BY MR. FAES:
Q I understand. I'm asking about polypropylene mesh.
And the TVT is made out of polypropylene. Do you understand that?
A Correct.
Q Do you have an opinion as to whether or not excessive contraction or shrinkage of tissue surrounding the mesh can occur with polypropylene mesh?
A So there is -- there is data which claim that. There is data which show and what's really happened for TVT/TVT-O -- I'm just going to express that specific to TVT/TVT-O -- that is a no event, even if it exists. Yes, it was shown in at least two, three studies that it really did not even happen.
Q So a follow-up to that question is that you'd agree with me then that you don't think that that's a reasonable -- reasonable warning for Ethicon to give with regard to the TVT products, that excessive contraction or shrinkage of tissue surrounding the mesh may occur?
MR. ROSENBLATT: Object to form.
A I do not agree that, unless it's substantiated and there's abundance of evidence. I don't see any point doing that.

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(Interruption; off the record.)
BY MR. FAES:
Q Would you agree with me that before implanting a TVT or TVT-O device, you should inspect the quality of the mesh edge for any fraying, and if the mesh edge is frayed, you shouldn't use that mesh in a patient?
MR. ROSENBLATT: Object to form. Compound.
A I never do that.
BY MR. FAES:
Q So you -- okay. He's right, it was compound. Let me ask it a different way.
So you never -- you never inspect the quality of a mesh edge of a TVT or TVT-O for fraying prior to implanting it?
A I do not do that.
Q If you were to see that the edge of the mesh were frayed, would you go ahead and use that or do you believe -- or would you -- or sorry, kind of interrupted you there. If you saw -- let me strike that and start over. I'm getting all flustered here.
If in the course of events you saw that the edge of a TVT or TVT-O mesh was frayed prior to implanting it, would you proceed with implanting that device or would you go and get a new device that didn't have a

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frayed edge?
A I don't check for that. So I don't even know what I would do in that case.
Q Do you have an opinion as to whether or not a frayed edge of a mesh can cause complications to a patient such as an erosion?
A I do not believe that.
Q You don't believe that a frayed edge of a TVT or TVT-O mesh --
A No, I do not believe that, and that's based on all my literature review, high-quality studies. I don't remember in any one of them this being mentioned as a risk.
Q So you've never heard -- strike that.
Have you ever heard a warning provided by any manufacturer of a midurethral sling that before implanting a device, you should inspect the quality of a mesh edge for any fraying, and in the event that the mesh edge is frayed, that you should discard it and open a new unit?
A I'm not aware of that.
Q Assuming that a medical device company had information that suggested that a frayed edge of a mesh could lead to patient complications, do you think that would be a reasonable warning for the device company to

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put in the IFU?
MR. ROSENBLATT: Object to form.
A I would look at that piece of evidence and understand why that is, because it doesn't make sense to me.
BY MR. FAES:
Q Doctor, I'm going to mark Exhibit Number 13 to your deposition. And this is the current IFU for the Desara SUI sling.
MR. ROSENBLATT: What is the source?
MR. FAES: What do you mean "the source"?
MR. ROSENBLATT: Did you just pull it off the website though?
MR. FAES: Desara.
What is that?
MR. ROSENBLATT: Did you just pull it off the website?
MR. FAES: It's Desara's IFU.
BY MR. FAES:
Q So if you can turn --
MR. ROSENBLATT: I want to know what the source is though and when it's from.
MR. FAES: The source is Desara Medical.
THE WITNESS: Caldera Medical.

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MR. FAES: Yes, Caldera Medical, the Desara sling. I'm probably pronouncing it wrong.
MR. ROSENBLATT: What is the source? Can I go online and find this version?
MR. FAES: I don't know if you can or can't. You'd have to check.
MR. ROSENBLATT: Did you get this from their production?
MR. FAES: No.
MR. ROSENBLATT: Where did you get this information?
MR. FAES: I told you. Caldera Medical. It comes from Caldera Medical.
MR. ROSENBLATT: Like this?
MR. FAES: Yes.
BY MR. FAES:
Q Anyway, I'm going to proceed with my question. If you can turn to the "Tabs" item. Can you read that highlighted portion for me?
A It reads: "Before implanting this device, inspect quality of the mesh edge for any fraying. In the event that mesh edge is frayed, please discard and open new unit."
Q Had you ever seen a warning for that in an IFU

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for a midurethral sling before today?
A This is the first time I see anything stated that way in an IFU.
Q Is that information you would have liked to have had before forming your opinions in this case?
MR. ROSENBLATT: Object to form.
A For now approximately 20 years I've been using this, this is new information for me.
MR. ROSENBLATT: And I also object to the extent you're using documents from other litigations that have been produced. And if they have not been produced in the Ethicon litigation -- I don't see a Bates stamp on this.
MR. FAES: It's a public document. It's not subject to any protective order. I will state that for the record.
MR. ROSENBLATT: Okay. Well, I don't know that. So I'll just maintain my objection.
BY MR. FAES:
Q So is it correct that no one from Ethicon and Johnson & Johnson has -- had ever told you that a frayed edge of a mesh can potentially lead to complications; is that accurate?

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MR. ROSENBLATT: Object to form.
A Can you define "fraying" for me? You're using "fraying" asking me questions and using a term called "fraying." What does that mean?
Q What does that mean to you, Doctor? What's the term "fraying" mean?
A It could mean many things. Since you are asking me the questions, tell me what exactly "fraying" you are asking about means and I'll answer the question.
Q Well, let me back up. Has anyone from Ethicon and Johnson & Johnson ever come to you and told you that there is a potential that the TVT or TVT-O mesh might fray, using that word?
A I've not heard that.
Q If someone from Ethicon and Johnson & Johnson did come to you and used that word, would you ask them, "Well, what do you mean by 'fraying?'"
A Definitely. You are asking me my opinion on something. I need to understand exactly by correct definition. Because "fraying" is not very extremely scientific word. May carry different weights with it.
Q Doctor, I'm going to hand you what's been marked as Exhibit Number 14 to your deposition. And I'll represent to you that this was a document produced by Ethicon and Johnson & Johnson in litigation.

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And specifically I want to have you turn to this page right here and ask you: Have you ever seen a TVT device that looked like that before?
A So I personally think that, having done slings, all kind of mesh over the years, this is a no event to me. And that's all I'm going to say. I don't see this as a problem.
Q So your answer is: You have seen a TVT mesh that looks like that before?
A I have used --
Q And I want to make sure we are both looking at the same page.
A I have used mesh in many different forms from different companies. I've seen the edges sometimes becoming like that. It has not been a problem, and I don't think that has been studied in any way which would show that it causes extra risk to the patient in terms of mesh erosion, exposure, chronic pain, or anything else.
Q So just for the record, we are looking at the page on Exhibit Number 14 ending in 02180829. Right, Doctor?
A Correct.
Q Because there is more than one picture, I just want to be clear what we are looking at.

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So it's your testimony that you have seen mesh that looks like that before and you went ahead and used it when you've seen that?
A Correct.
Q If anyone had -- from Ethicon and Johnson & Johnson had ever told you that there was a potential that a frayed mesh like this could potentially cause complications for the patient, you would have listened to them, right?
A I would really ask for the evidence, what study they did.
Q But no one -- I think we have already established no one from Ethicon or Johnson & Johnson has ever told you that, right?
A I've not been told that.
Q Okay. Doctor, I'm going to hand you what's been marked as Exhibit Number 15.
Actually let me back up. Have you ever seen the document marked as Exhibit Number 14 before?
A I don't remember seeing this.
Q Do you recall if it's a document that you reviewed and relied on in forming your opinions?
A I don't remember. I don't remember.
Q Okay. I'm going to hand you Exhibit Number 15 and I'm only -- I'm really only doing this because you

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asked me about what the definition of "fraying" was.
So this is another document produced by Ethicon and Johnson & Johnson. And this document's actually public record; you can see the file stamp up at the top.
But specifically I'm going to ask you to turn to the second page ending in 9313. You see it's got a complaint summary for TVT-Base and TVT-O. And you see that the -- if you look at the top, the number one category of complaints, with 29 complaints and then 22.4 percent of the complaints, is mesh fraying/roping for the TVT.
Do you see that?
A Correct.
Q Has anyone from Ethicon and Johnson & Johnson ever told you that the number one complaint that they have with the TVT product is mesh fraying and roping?
A No, because --
MR. ROSENBLATT: Object to form.
A Because it's irrelevant. What is the point of discussing that with me?
BY MR. FAES:
Q Well, I guess there is no point if Ethicon and Johnson & Johnson have never told you that --
A Correct.

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Q -- it caused complications.
A I'm glad they're not wasting my time with that.
Q Have you ever seen complaints to the company where doctors have complained to physicians that they in fact have had an erosion from a roped or frayed mesh?
A Look, I don't pay attention to what that -- those kind of anecdotal experiences. I go by large randomized trials, which have been done more than a hundred times on TVT, maybe 60 times on TVT-O. And they don't talk about those things. So it's of no information for me, regardless.
Q What about -- what about published case reports, do you pay any attention to those?
A Case reports can lead to something. And case report means something when you have no access to prospective randomized long-term data.
But this is one area, we are so fortunate to have hundreds of them, I don't go to case reports for that.
Q So am I correct that if you -- if you saw a case report or multiple case reports reporting a complication or erosion from a roped or frayed mesh, you would just disregard those reports?
A Look, when millions of other patients didn't have that, and thousands of patients in the studies didn't

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have that, there's no mention about it, I only look at it, be aware of it.
Would I use it in my practice? I haven't. Because I haven't seen it in reliable resources, which is Level I evidence produced so many times on TVT and TVT-O. They don't talk about it.
Q So do you consider such case reports or do you just disregard them?
A They are valuable if we didn't have all these bulk of information, the best ever, in both urology and gynecology world, produced for TVT and TVT-O.
I don't look at the case reports. There will be case reports of all kind of weird monster cases. You want to know about them, but they are huge outliers. Because that's why they don't show up in these big studies.
So the results of big studies matter. That's why we do randomized big studies.
There is nothing else in my world which has been more studied than TVT and TVT-O. Nothing.
Q So if a person has a complication from a roped or frayed mesh, do you think that person cares whether or not they are an outlier, or are they concerned with the adverse event that they have experienced?
A That's N-O-1. N-O-1 in science means zero,

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nothing, zilch. You want a big denominator.
So that one experience, it's impossible for me to conclude the roping or fraying, whatever you are describing -- and the definition is not clear in your mind as well -- that for me to conclude that that caused it. Maybe the doctor didn't put it in the right place.
Q So if -- in your opinion, if the numbers are small enough, that those complications don't matter to you?
A That's not what I'm saying. That's so funny that you are saying that, because -- because you look at the denominator of prospective studies. You don't look at one case report to make a conclusion on a study -- on a procedure.
If they keep coming back, there's like hundreds over the years, then we must design a study to look at it. But that has not happened. So that's why they will remain as outliers. That's why they became case report.
Case report is like so unbelievably rare thing happens, we want to share with other people. But that does not guide us for the future or for an IFU, for example.
Q Doctor, on page 17 of your report, you state that

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you've been using TVT for 20 years and have used both mechanically and laser cut TVT and TVT-O. You can attest to the fact that you have not noticed any clinical difference between mechanically cut versus laser cut mesh with respect to effectiveness or safety in my clinical practice or in the medical literature.

Do you see that?

A Correct.

Q Is that an opinion that you intend to offer in this case: that in your clinical practice, you haven't noticed any clinical difference between mechanically cut mesh or laser cut mesh?

A Correct.

Q But I think, as we covered earlier, you don't even know how to tell the difference if a device is sitting on the shelf whether or not it's mechanically or laser cut mesh, right?

A Correct. I have no way of knowing that.

Q So your opinion that you haven't noticed any clinical difference between mechanically cut versus laser cut mesh with respect to effectiveness or safety isn't a result of any kind of formal analysis or study that you've done on your own patients, correct?

A That's correct.

Q You also go on to state that there is no clinical

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data to support the difference, and in fact recent studies analyzing this issue have confirmed the lack of any clinical significance.

Do you see that? Is that an opinion you intend to offer in this case?

A Yes.

Q And then you cite two studies here, a Rusavy and a Thubert.

A Correct.

Q Are those the only two studies you are aware of that are specifically comparing the mechanically cut to the laser cut?

A At the time of this report, preparing this report, I was -- I specifically reviewed those two to make that conclusion. Maybe there's other.

Q At the time you wrote this report, those are the only two studies that you're relying on for that conclusion, right?

A I had access to, yes.

Q Okay. The Thubert study, for example, that was a study comparing the TVT-Exact versus the TVT, right?

A Correct.

Can you give it to me? Let's just mark it.

Q We are at 16.

MR. FAES: Sorry I don't have another

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copy, Paulie. I wasn't planning to give it to him. I'm sure you know that study well.

BY MR. FAES:

Q So this is versus the Exact and the TVT, right?

A Correct.

Q I think you stated earlier in the deposition that you didn't know whether the Exact was laser cut or mechanically cut. Isn't that accurate?

A Right now, I didn't remember which one was cut, because I don't pay attention to it.

Q Now, with regard to the TVT arm, is there anything in the study that indicates whether the TVTs used in this study were mechanically cut, laser cut, or were a combination of the two?

A I have to go back and review. It's hundreds of papers I reviewed for this. I can't really remember exactly. So give me a chance to read this whole thing one more time and I will answer that.

So maybe -- so it doesn't say anywhere in this paper whether one was laser cut versus the other one was not.

Does it say it anywhere in this study?

Q I don't believe it does, at least not with regard to the TVT-O arm.

So how did you conclude from this article, if it

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doesn't state whether the TVT retropubics were mechanically cut or laser cut, that it supports your conclusion that there's no clinical data to support the difference?

A I was probably told by my lawyers, who provided these papers, that this was a significant paper regarding that. And that's why I use it as a -- so TVT -- Exact and TVT differed in how they were cut. So that's why that conclusion could be because of that.

Q So the other study that you reference in support of this conclusion is the Rusavy article, correct?

A Right.

Q And in that article, don't they conclude that the laser cut and the mechanically cut TVT-O actually do differ in terms of handling and insertion and also in biomechanical properties such as stiffness and elasticity?

MR. ROSENBLATT: Can you hand him a copy?

A I know that paper very well.

MR. FAES: What are we on, 17?

MR. ROSENBLATT: Yes.

THE WITNESS: Yes.

A Yes, it did find differences in those properties. However, it didn't make any clinical significant

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difference.
BY MR. FAES:
Q Well, if you look on page -- the second to last page, about the third paragraph down, where it states "Following a few cases of urinary retention after laser cut tape, implantation before the commencement of the second RCT, a slight change in the tensioning of the tape was made. The laser cut TVT-O was implanted more loosely. This change in practice was well demonstrated by early ultrasound measurements and comparable to -- and comparable early tape release rates."
So they actually changed the way that they implanted the laser cut mesh in the original trial and then went and did a retrospective analysis of that, right?
A So I was -- I would thank that study, if I was the reviewer of that paper, for putting that information in the discussion and not studying it. So actually it's a bad way of reporting outcomes.
So I -- unfortunately, as much as I agree with their conclusions regarding there's no clinical significance, that is probably a flaw of the study that that was not studied well.
Q Right. Because a change in the way that you implant the device can affect the results, right?

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A So, therefore, there's so many other things, maybe, they were not doing right, so all of that actually is a problem with it.
But the outcome, clinical outcome, is what matters really. And that didn't change anything. Comparison of two years subject and object, surgical outcomes was similar.
Q Right. But that we don't know if that conclusion was confounded by the fact that they changed the way they were implanting the laser cut mesh, right?
A It's inconclusive regarding that.
Q And you can't tell -- you've stated that you can't tell the difference when you pull it off the shelf between the mechanically cut mesh and the laser cut. So you tension them the same, right?
A So my own results for my TVT placement or sling placement, I am at, based on my own studying of my results, 90 percent efficacy is what I'm looking for and I'm getting it and I'm very happy about it. Therefore I never thought that would there would be a need to really study that.
And I think I can tell you at this point the world of urogynecology has passed that. They are not looking at it, laser or mechanical cut. I'm not sure why you guys make it a big deal. It's -- it's to us

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irrelevant.
Q Well, you'd agree with me that no one then -- that no one from Ethicon and Johnson & Johnson has ever come to you as a long-term consultant and trainer for them and told you that you need to tension the laser cut mesh differently as opposed to the mechanically cut mesh, right?
MR. ROSENBLATT: Object to form.
BY MR. FAES:
Q Nobody's ever told you that?
A Because there's no study to say that they should. Because there's no study to say that they should.
And I believe there's all other of the mesh sling products which were cut one way or the other, and their studies also support that it didn't matter. I mean they all came to the same approximate efficacy rate, which is 85-95 percent range.
Q And you'd agree that one of the conclusions of the study is that they were able to demonstrate that not all TVT-O tapes are the same, right? It states that on the last page under "Conclusion."
A Right. I said that is like a speculative sentence, and I would say that's not a true conclusion should be allowed in a conclusive statement. But they could say that.

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So I have no doubt Ethicon, with its resources, does that job better than any other company, to standardize their products.
Q And they actually conclude, contrary to what you state, that tape which is more resistant to elongation, meaning a stiffer mesh, should be inserted under the urethra less tightly to prevent urinary retention?
A I think all of them have to be placed not tightly. That's really -- like if they are placing anything tightly, they are wrong anyway, so...
Q But they are describing a difference in the way that they place the laser --
A Excuse me. Subjective.
Q -- versus the mechanically cut mesh, which no one has ever described to you, right?
A So what they did with tensioning is very subjective, not studied. So that is, again, not any information I would use in any set or form.
Q So on page 18 of your report under -- it's number 2, you state that "Midurethral slings made of monofilament polypropylene is the most extensively studied anti-incontinence procedure in history."
Do you see that?
A Yes.
Q When you say it's the most extensively studied,

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what do you mean by that? Do you mean in terms of quality of data, number of patients, number of studies, or all of the above?

A Okay. It really is all of the above.

Q So you believe that it -- that the monofilament polypropylene midurethral sling is the most extensively studied in terms of quality?

A Quality, quantity, and years.

Q Are you aware that the Cochrane analysis also concludes that despite the body of data out there on midurethral slings, that the overall quality of the data is poor? Have you seen that conclusion?

MR. ROSENBLATT: Object to form. And can you specify which year Cochrane review you are referring to?

MR. FAES: I'm just asking if he's ever seen that conclusion.

MR. ROSENBLATT: Object to form.

A I probably didn't read that comment. Because I believe if I did, I would write a letter to them. Because I am extremely --

I don't think there could be any other body of evidence which has strongest, more convincing data, that study design. There is nothing. So I'm not sure why they say that, what they regard as best study

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design.

Q So if it's the most extensively studied anti-incontinence procedure in history, what is the second most extensively studied anti-incontinence procedure?

A Then, you know, this in comparison, this would be like one is 100, the other one is like 4, possibly. That would be Burch autologous slings, somewhere there. That much, that far distance in between.

Q I'm talking about quality right now, not numbers.

A Quality and numbers. Everything. Everything included for Burch or autologous fascial sling, the -- the size of the data, quality, quantity, years, all of that, you cannot even compare with the other two, which are following from far behind, and they've pretty much been abandoned today.

Q But you'd agree then that basically number 2, 2 and 3, are behind the monofilament polypropylene sling in terms of being extensively studied in terms of quality as the Burch and the autologous fascial sling?

A No, no, I do not. I'm sorry, I misunderstood your question. I might go back and change it maybe, I don't know.

But this is what I'm saying. No, no, specific to anti-incontinence surgeries, if you're asking, yes,

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there is nothing else.

Actually, maybe I might even say that like needle suspension procedures might have been studied more than the Burch, except they failed to show long-term success, that's why they are not around anymore.

There were procedures such as Stamey, Pereyra, Gittes procedures, at some point they were quite fashionable, but studies show that they didn't last too long. Maybe they were studied more than Burch.

Q So what other anti-incontinence procedures did you study when you made your conclusion that monofilament midurethral slings are the most extensively studied? What was your basis for comparison?

A Burch. So, first of all, here -- well, exactly. So Burch. Autologous slings. Needle suspension procedures, including those I just listed. Bulking agents. Kelly-Keenedy suturing. All of these are considered surgical procedures to correct stress incontinence.

Among all of them, by far, midurethral monofilament slings have been studied more.

Q So what is the second most extensively studied anti-incontinence procedure in history?

A I can't say with 100 percent certainty which one

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it is. But I can tell you there is literature to make comments on the efficacy and safety of Burch, autologous fascia slings, and those are the anti-incontinence surgeries I just mentioned.

Q If you can't tell me what is number 2, what is the second most extensively studied anti-incontinence procedure in history, what criteria did you use to come up with the number 1, which, in your opinion, is the monofilament polypropylene sling?

A A literature search will help you immediately see. If you pull 100 studies on anti-incontinence procedures, easily 90 of them will be on slings, period. So I don't have to find which is second or third. So remaining ten is now shared by everything else.

Q But how do you determine the quality of those studies compared to the quality of other studies?

A I studied all those studies too. So like 20-something years I've been doing it. Obviously for me to conclude that midurethral slings are better, I must have studied all the other studies which existed for everything else before, and based on that, I could see most studied for Burch was retrospective series.

If there was any comparison, it happened until -- it didn't happen until TVT came out. And the first

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good comparison was SISTEr's trial between Burch, like which could come close to the comparison done. Like Thomas trial, SISTEr's trial, compare those two, autologous fascial slings, and actually they both performed awfully in those studies. They really didn't perform that well.

Compare the Thomas trial data yourself, you'll see how actually they weren't -- I wish there was a TVT arm there, except at that time they were not guided right. That already when they designed SISTEr's trial, the majority of gynecologists and urologists had already switched to TVT. I wish they included that as an arm and we wouldn't be talking about any of these things today. They didn't.

So then there was Ward/Hilton study, which compared TVT against Burch. And showed that TVT is same, plus a lot easier to perform, a lot easier on the patient, so it was a no-brainer.

Q So you are relying heavily on the quantity of the studies that are available out there for your opinion that the quality is the best with the polypropylene slings; is that accurate or not?

A That is very inaccurate, whatever you just stated, so...

Q You've answered my question.

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Doctor, on page 20 of your report, you talk about "Plaintiffs' Safer Alternative Designs." Do you see where I'm at?

A Correct.

Q You say that "Native tissue and suture repairs are not held to the standards which TVT sling has been to because they are not medical devices."

A That's such a true statement.

Q So it's your opinion that the Prolene suture is not a medical device?

MR. ROSENBLATT: Object to form.

A Prolene suture is not a medical device. But it's a foreign material. And I would worry about if it erodes through as much as I would worry about mesh erodes through.

BY MR. FAES:

Q Do you know whether or not the -- whether or not the Prolene suture actually has an IFU, or Instructions For Use, like the TVT or not?

A Prolene suture, 1960s it was developed. And I'm not sure IFU was needed for it. I'm not sure what the standards were then when Prolene suture was introduced.

Q So as you sit here today, you are not sure whether or not the Prolene suture has an IFU, or Instructions For Use, or not, correct?

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A Since it goes through FDA, it must have some regulatory process. 1960s, I'm not sure what the standard was. And whether sutures are held to the same standard as medical devices.

Q Doctor, have you studied the question at all of whether or not the Prolene mesh used in the TVT or TVT-O is cytotoxic?

A I have studied that topic, yes.

Q And do you have an opinion in that regard, whether or not the TVT mesh is cytotoxic or not?

A Yes, I do have an opinion.

Q What is that opinion?

A It's not cytotoxic.

Q Is that disclosed anywhere in your expert report?

MR. ROSENBLATT: Did you just ask him about it?

MR. FAES: Yes.

MR. ROSENBLATT: Okay. It's fair game. If you want to ask him about questions, he'll give you his opinion.

A I'm not sure if it's here.

BY MR. FAES:

Q Okay.

A I'm not sure if it's being discussed. So I talk about degradation and carcinogenesis. I don't think I

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have any specific paragraph to it.

Q Let me ask you this: Do you know what happens when cells in the body are exposed to a cytotoxic substance?

MR. ROSENBLATT: Object to form.

And, Andy, am I correct that you are now asking him about opinions that he's not offering?

MR. FAES: If he's not offering it -- he just said he was offering it. So is he offering it or not, because it's not in his expert report?

MR. ROSENBLATT: Okay. You're just going off an outline as opposed to what's in his report.

MR. FAES: No, I'm asking if he's going to offer that opinion. And it sounds like the answer is no because it's not in his report. So I'll stop with that line of questioning.

THE WITNESS: Okay.

BY MR. FAES:

Q Do you hold yourself out as having any expertise or specialized knowledge regarding the type of mesh used in the TVT?

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A Yes.
Q And what is the basis of your expertise? Just your clinical experience?
A No. I've been in designs of these products, as we discussed earlier.
Q Do you have any expertise or specialized medical knowledge regarding whether or not a one-millimeter pore size when the mesh is used in the body has any advantages or disadvantages to the patient?
A So all the studies about pore size, we still don't know with certainty that it makes a big difference. But the conclusion with I think the bulk of information we have is, it would be safer to have larger pores. So that's why today, we all moved on to larger pore mesh for both incontinence and prolapse surgery.
Q And in fact you'd agree that the Restorelle mesh that you currently use for repair in pelvic organ prolapse is substantially lighter than the mesh used in the TVT, right?
A That is correct.
Q And you'd agree with me that a lighter weight mesh can offer benefits to a patient as opposed to a heavier weight mesh, right?
A That is not correct. It depends on the

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application of the mesh. What purpose the mesh is inserted will help me tell what density mesh or what weight mesh would be most appropriate.
Q You'd agree with me generally that whatever the application is, whether it's stress urinary incontinence or pelvic organ prolapse, it's best to select the lightest weight mesh that will still do the job, right?
MR. ROSENBLATT: Object to form.
A That's not correct.
BY MR. FAES:
Q No?
A That is really not correct. Light possible mesh, but not the lightest mesh.
They tried to introduce, let's say, Restorelle type of mesh for stress incontinence. But they decided not to bring it to the market because it didn't perform the same way.
So Coloplast, which is the maker -- I'm not sure if I can make these comments, I think I can -- still uses the former mesh, which came from Mentor, and they did not use the mesh they got with the acquisition of Mpathy, which made the Restorelle mesh.
So that statement is wrong, because application for stress incontinence in the suburethra might be

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different than when it is inserted in the entire interior vaginal compartment.
So yes, light mesh makes sense there, but not for necessarily suburethral application.
Q Well, you know from your expert report on page 20, you discuss the Okulu study and mesh that was used -- a lighter weight mesh that was used for stress urinary incontinence. Do you see that?
A Correct.
Q Do you know what mesh was used in that study?
A So I don't remember right off the top of my head right now.
Q Are you familiar with the TVT-O partially absorbable mesh product?
A Oh, yes. Right. That actually also didn't perform as well, so...
Q Well, you know that the TVT-O partially absorbable mesh actually contained the same mesh that was used in the Okulu study, right?
MR. ROSENBLATT: Object to form. Lack of foundation. Misstates the reality.
A I disagree with that.
BY MR. FAES:
Q Why do you disagree?
A Because it's not the same mesh.

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Q You don't believe that the --
A For many different properties, they are not the same mesh.
Q You don't believe that the Okulu study used the Ultrapro mesh?
A It was cut in a different way and inserted in a different way. So you cannot extrapolate and compare those studies when the method was not the same.
Q Are you aware that Ethicon and Johnson & Johnson actually prepared a report in which they included that the TVT-O partially absorbable was substantially equivalent in terms of safety and efficacy to the TVT-O product?
A I am -- I am not aware of that. But what I'm aware of is TVT as it was first designed in 1996, which I still use, performed very well regarding mesh exposure.
So I don't personally see as a clinician, based on the quality of the data, that I need any change in the material of TVT, when it is working so well.
Q So you don't see any need to change the material even if it can reduce the complications?
A Complication rate, we are talking about 2 percent. I wish all procedures had about 2 percent complication rate.

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Q So my question is: You don't think it's necessary to come down any more from 2 percent? If you can go from 2 percent to 1 percent or even half a percent, you don't think the company should do that?

MR. ROSENBLATT: Object to form.

A No. I would love to eliminate any complication. But I know, being an expert in mesh territory, I'm not sure if you will ever get there, so -- unless some new revolutionary product comes out.

MR. FAES: Go off the record for just a second.

MR. ROSENBLATT: Sure.

(Discussion off the record.)

BY MR. FAES:

Q Doctor, we are back on the record after a short break. Are you ready to proceed?

A Yes.

Q In your expert report on page 21, you talk about the degradation of TVT-O and TVT-O mesh. Do you see where I'm at?

A Yes.

Q You'd agree -- would you agree with me that there is a debate going on as to whether or not the TVT and TVT-O mesh degrades?

A Correct.

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Q And you'd agree that there is a substantial amount of peer reviewed medical literature that concludes that the TVT and TVT-O mesh does in fact degrade, right?

MR. ROSENBLATT: Object to form.

A I disagree with what you just said.

BY MR. FAES:

Q You don't think there is a substantial number of medical -- published medical articles that reach that conclusion?

A "Substantial" is the wrong adjective.

Q Would you agree with me that there is more than 25 peer reviewed published articles that conclude that polypropylene mesh used in the pelvic floor does degrade?

MR. ROSENBLATT: Object to form.

A I'm not sure how many. But whatever exists there doesn't seem substantial to me.

BY MR. FAES:

Q And is it your opinion in this case that the TVT and TVT-O mesh doesn't degrade, or that if it does degrade, it's not clinically significant?

A Okay. Actually, there are also studies which show that it really does not degrade. And if -- even if it does, just like you are saying, it would not

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change the clinical significance, because, again, we regard high quality, large prospective trials as the standard when we make decisions.

So we have 17-year data, at least two of them, and that has not been any problem, even if there were any degradation, but there is enough studies which are on this end of the spectrum. So they cancel each other out, in my opinion.

Q How did you make the determination to accept the studies that you list here that conclude that the mesh doesn't degrade and reject all the ones that don't?

A Based on clinical data. Clinical data trumps everything, when especially it is the quality we have for TVT and TVT-O.

Q So is it going to be -- do you intend to offer an opinion in this case that the polypropylene mesh in the TVT and TVT-O does not degrade?

A I do not believe it does.

Q Okay. And in reviewing -- and in forming your opinion in this case, did you ever review the testimony of Ethicon and Johnson & Johnson's corporate representative on this topic as to what he stated whether or not the mesh degraded?

A Right. There is opinions in Ethicon's circles that it -- some tests, experiments, it showed some

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changes, but it was something to do with the preparation of the specimens, which actually indicated that when it was studied better, it didn't become a problem, they weren't able to demonstrate it.

Q But did you understand that in this case there's actually been a person named Thomas Faribault that was designated to speak on behalf of the company on the issue of whether or not polypropylene degrades and that that individual did offer sworn testimony under oath?

A I wasn't aware --

MR. ROSENBLATT: Object to form. Lack of foundation.

A I was not aware of that.

BY MR. FAES:

Q And you didn't review that testimony in forming your opinions in this case that the mesh does not degrade, right?

A I don't remember reading that sort of testimony.

Q Do you think it would be important to review the testimony of the person that Ethicon designated as the most knowledgeable person on this topic before reaching your opinions?

A As a scientist, I'm curious, I like to know all of that. Except I really still don't think my opinion would ever change, because I rely on, methodologically,

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highly rated papers up there, like the Level I studies, about 100 of them, which those give me the guidance. So animal studies or in vitro studies, those things really do not matter when clinical evidence doesn't show that it has any relevance at all.

Q And have you reviewed the material safety data sheet for the raw polypropylene material that goes into the TVT and TVT-O products? Have you ever seen that before?

A I'm not sure. If you show me a document, maybe I'll remember it now. I've read so many things over...

Q Okay. Let me ask another question. Are you aware that the manufacturer of the raw material, the polypropylene that goes into the TVT and TVT-O, has warned that strong oxidizers, such as peroxides, are incompatible with the plastic in the TVT and TVT-O?

MR. ROSENBLATT: Object to form. Foundation.

A I'm not aware of that.

BY MR. FAES:

Q And you know as a urogynecologist or pelvic floor surgeon, if you will, that the female vagina is a natural source of peroxides, right?

A Correct.

Q Have you ever studied the question of whether or

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not the peroxides in the vagina affect the composition of the TVT or TVT-O mesh?

A They are really irrelevant.

Q So you've never studied that question; is that accurate?

A I never studied that question, as I don't see any merit studying it.

Q I think we touched on this a little bit, but I want to make sure I have your responses clear to this particular line of questioning.

Do you know whether or not scar contracture around the mesh can occur with TVT or TVT-O?

A Scar contracture occurs everywhere we cut. So -- and every human being's response to surgical process is very different. And that applies to placement of implants, wherever they are. So I could just put stitches in there, that causes enough scar contracture there. So, to me, it really is also irrelevant.

Q Well, do you know whether or not scar contracture with polypropylene mesh was a problem that Ethicon engineers were trying to solve?

MR. ROSENBLATT: Object to form.

A TVT and TVT-O, it has not been a clinical issue, period.

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BY MR. FAES:

Q So you then wouldn't agree that scar contracture or scar tissue formation can translate into procedural complications?

A It is not. It doesn't happen. If it did, then today the urethras of all people, millions of women we placed slings, would be cut off with the contracted scar tissue, TVT and around it.

Q So you then would disagree that scar contracture from the TVT or TVT-O can cause pain?

A Scar formation can cause pain in any surgery. And it could happen when you have TVT-O or TVT.

Q So you'd agree then that scar contracture around the TVT or TVT-O mesh can occur and can potentially lead to pain, right?

MR. ROSENBLATT: Object to form.

A Scar formation is just a process which happens in all kind of surgeries, including pelvic floor surgeries, including anti-incontinence surgeries, with or without mesh use. And scar formation, as we have been saying, in the vagina can cause pain, whether it was used for mesh placement or not.

BY MR. FAES:

Q So I'm not sure if I got an answer to my question there. Because I was asking -- I'm asking specifically

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about TVT and TVT-O. I'm not asking about pelvic floor surgeries or any other surgeries. So I'm going to ask that the reporter read back the last question.

MR. ROSENBLATT: Object to form. Asked and answered.

(Question and answer read back.)

A That answers your question.

BY MR. FAES:

Q I don't think it does. It's a yes or no question. Can you answer that question yes or no or not?

A I cannot answer yes or no, sorry.

Q So you'd agree with me that you can't answer the question yes or no as to whether or not scar contracture can occur around the TVT and TVT-O and whether that can cause pain; you can't answer that one way or another?

MR. ROSENBLATT: Object to form. Asked and answered.

A Yes or no answer will not serve this process right. So I decline to answer in any other form.

BY MR. FAES:

Q Would you agree that scar contracture can occur around the TVT or TVT-O mesh in general -- strike that.

Can scar contracture occur around the TVT and

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TVT-O mesh?
A Yes, it can.
Q Can that scar contracture -- can -- well, strike that. Let me back up.
Can scar contracture lead to pain?
A Yes, it can.
Q Can scar contracture lead to discomfort during sex?
A Yes.
Q Can scar contracture lead to erosion?
A No. And all the answers I gave are also valid for all the other pelvic floor surgeries I do without implantation of mesh.
Q Would you agree with me that a mesh could potentially be too stiff to be used for the treatment of stress urinary incontinence?
A If you don't use the right material, it could be too stiff.
Q Right. So you agree that it's possible that someone could introduce a material for the treatment of stress urinary incontinence and that material could turn out to be too stiff after testing and clinical studies were done, right?
A No. No. No. Not like that. Not like that. That is wrong, how you said that.

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So the way you test on tensile strength in the lab, stiffness does not necessarily almost always apply in clinical medicine. We have seen that many times. So I'm not going to translate that to the fact that it's going to cause problems there. So stiffness might be an irrelevant property.
What matters, again, is one thing: In the clinical use, after millions of use, what has happened? And the best studies to study that is the Level I randomized trials and also the ones which look at it in a systematic fashion and meant to analyze them.
When you look at them, what TVT and TVT-O did, regards to whatever it was found in the lab with stiffness, performed very well.
Q So my question is though, is it hypothetically there could be a mesh out there that could turn out to be too stiff for the indication of stress urinary incontinence, right?
A What is stiff for a clinical use? That also has not been described.
Stiff in the physics lab is one thing, mechanical lab is one thing. Stiff in tissue is another thing. We don't understand that yet.
Q On page 23 of your report, you state that "The product IFUs for the TVT and TVT-O appropriately admit

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well-known risks that can occur with any pelvic floor surgery with or without mesh." Do you see that?
A Yes.
Q What risks?
A 23, right?
Q Yes.
A Yes.
Q It's the middle of the page. What risks do you think that the IFUs for the TVT appropriately omit?
A So the ones we know in any surgery which we do.
Nerve damage. Yes, I can cause nerve damage without touching any foreign material, without insertion of even like a permanent stitch. I can do it with a Vicryl stitch. I can do it with patient's -- her own tissue inserted there.
Organ damage. I've seen it happening in C-sections, hysterectomies, or any kind of surgery.
Bleeding, hematoma. Pain, dyspareunia. Those are inherent in all these surgeries.
Hysterectomy will cause chronic pain. Not in every case. It will.
Same for implants, because it's in the pelvis. It will cause dyspareunia. All of that. So they omitted them most of the time.
But then they had to change it, because that was

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needed because of the litigation going on. And that was more like professional liability purposes, I guess, they were instructed to do that.
But in my opinion, I -- as a surgeon, I know that these will happen whatever I do in the pelvis.
Q So it's your opinion that all those risks -- nerve damage, organ damage, bleeding, hematoma, pain, dyspareunia, were just added due -- because of litigation and are of no help to doctors or patients?
A I didn't say that. What I'm saying is doctors already know. As long as -- as soon as they step their foot in the OR, they are potentially going to have some of these problems and they are prepared for it. And no medical device company should tell that. They are all well educated on that.
If they are not, then they probably should not even perform surgeries.
Q Do you know when the adverse events of nerve damage and organ damage were actually added to the TVT IFU?
A 2015.
Q Would it surprise you to learn that they were actually added in April of 1999?
A They were in the IFU in April of 1999?
Q Were you aware that there was an update to the

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TVT IFU -- I'm sorry, I misstated that.
That's right. Were you aware that there was an update to the "Adverse Reaction" section of the TVT IFU in 1999?
MR. ROSENBLATT: Object to form.
A I am not aware of that.
MR. FAES: Okay. I think that's all the further questions I have, subject to any follow-up from Paul.
MR. ROSENBLATT: Do we have any time left for it?
Can we go off the record for just a minute.
(Discussion off the record.)
CROSS-EXAMINATION
BY MR. ROSENBLATT:
Q Doctor, we are back on the record.
Your CV, which was marked as Exhibit 5, have you in fact published clinical studies, clinical information, reporting outcomes from midurethral slings?
MR. FAES: Object to the form.
A Yes.
BY MR. ROSENBLATT:
Q Would that include Ethicon's TVT devices?

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A Correct.
MR. FAES: Objection.
BY MR. ROSENBLATT:
Q In addition to contributing to the peer reviewed medical literature on TVT and other midurethral slings, do you continue to assess the published literature?
MR. FAES: Objection.
A Always.
BY MR. ROSENBLATT:
Q In addition to reviewing the medical literature, are you also on any editorial boards where you are reviewing submitted articles for potential publication?
A Yes, I was on the editorial board for Journal of Female Pelvic Medicine and Reconstructive Surgery.
Q And in your opinion, how has that experience helped you with your methodology in assessing the safety of midurethral slings?
A So since my training, I've always focused on studying best methodology. And I have run journal clubs in all three; now I'm the head of journal club at Yale ob-gyn department, and I have been on SGS, Systematic Review Group, and I've been on the editorial board, I've been ad hoc reviewer for 20 different journals. So my passion, to review papers.
Q So would it be fair to say that a lot of the

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materials listed on your reliance list are articles or publications, position statements, that you were already familiar with before you became involved in this litigation?
MR. FAES: Object to form.
A Correct. I have been reading up -- 80 percent of what I reviewed, I did it before ever knowing you.
BY MR. ROSENBLATT:
Q Okay. Prior to becoming involved in the litigation, what significance on the Oxford levels of evidence did you give to animal studies, bench studies, Petri dish studies, or company documents?
MR. FAES: Objection.
A The lowest. So level 5, level 6.
BY MR. ROSENBLATT:
Q And did you take the time to review some of the plaintiffs' general expert reports?
A Yes.
Q And did that help inform you to some of the claims that they are making in this litigation about the safety and the design of the TVT?
MR. FAES: Objection.
A Yes.
BY MR. ROSENBLATT:
Q And is that why you tried to respond to some of

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those claims in your report?
MR. FAES: Objection.
A That is true.
BY MR. ROSENBLATT:
Q And so, Doctor, you were asked some questions about -- well, strike that. We will get there.
Doctor, could you just briefly describe your experience in teaching residents and fellows.
A With what respect?
Q With respect to how you go about teaching residents and fellows how to perform midurethral slings and how you educate them on potential risks or complications of pelvic floor surgeries.
A So it's extremely important that, you know, we will raise the next generation of doctors who will perform all these surgeries, and probably take it to another level, so -- but it's also important to make sure that they practice in a safe zone.
And we take hours in classrooms, cadaver labs, in the OR, to make sure that we cover all the risks and complications. We use simulation in a dry lab before applying many of these things in the OR; that has helped a lot. And then we take them step by step, and we make sure that, at every step, safety is our priority.

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Q Doctor, are you suggesting that you don't just take the IFU, throw it at your residents, and say "You're on your own, good luck"?
MR. FAES: Objection.
BY MR. ROSENBLATT:
Q "Here's your -- you've completed your residency and your fellowship now."
MR. FAES: Objection.
A I don't think I have ever read the IFU together with the residents or fellows. We teach all of that at all times in the OR, after the OR, before stepping in the OR.
BY MR. ROSENBLATT:
Q Is an IFU intended to replace the clinical experience and education and training that residents, fellows, and pelvic floor surgeons are expected to have?
MR. FAES: Objection.
A Absolutely not.
BY MR. ROSENBLATT:
Q Doctor, you were asked some questions about some consulting work that you've done for other manufacturers. Have you done any consulting work in a litigation capacity for any other mesh manufacturers involving the pelvic mesh litigation?

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A No.
Q So to the extent you've been a litigation expert for a mesh manufacturer, Ethicon would be the only one. Fair?
A So far. This is the, ever, first one I accepted to be.
Q And the other consulting work that you described was more about consulting on the use of the product and various design features; is that accurate?
A Correct.
Q If you had noticed that any information in an IFU was misleading, would you have made that apparent to companies like Ethicon?
A Undoubtedly.
MR. FAES: Objection.
BY MR. ROSENBLATT:
Q And in your experience reviewing the TVT and TVT-O IFUs, did you see anything in there that you found to be misleading?
MR. FAES: Objection.
A Absolutely not.
BY MR. ROSENBLATT:
Q Doctor, you told us that some of your practice in treating incontinence is split 50/50 between the retropubic and transobturator slings. Fair?

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A That's correct.
Q Why is it that you would use both approaches for certain patients?
A As I was saying, I'm responsible in training next generation surgeons. And both of these skills are necessary because there might be different applications for every patient. So it's my job to make sure that they have gained both skills.
Q And do you know if surgeons -- or residents and fellows are expected to be able to perform retropubic and transobturator slings?
A Correct.
Q And in addition to being able to perform those two different procedures, are they also expected to be familiar with how to counsel a patient about the risks and benefits of those procedures?
A That's more important than anything else. My counseling includes sheets of papers in addition to regular hospital boilerplate consent forms.
Q And, Doctor, when was the last time you performed a TVT retropubic?
A Just yesterday.
Q Yesterday?
A I did two of them. And this morning. Both patients went home with the most pleasant smiles.

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Q And did anything that Mr. Faes asked you today give you any concern about implanting a TVT tomorrow if you had to?
MR. FAES: Objection.
A I'm not changing my management, because I am vindicated. I've been supported by literature and years -- 20 years of practice.
BY MR. ROSENBLATT:
Q And would it be fair to say all the opinions in your report -- we didn't discuss all of them today. But all of the opinions you express in your report, you hold those to a reasonable degree of medical certainty?
A Correct.
Q And are all of the opinions in your report based on your clinical experience as well as your review and ongoing analysis of the peer review published literature?
A Yes.
Q You were also asked some questions about mechanically cut versus laser cut.
Do you know when laser cut was introduced?
A I was told by you guys when it was introduced. I didn't pay attention to it.
Q And so would it be fair to say from at least 1999, when you started using TVT, to late 2006, when

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all of the TVTs and TVT-Os would have been mechanically cut, that you would have definitively then been using mechanically cut TVT or TVT-O?

MR. FAES: Objection.

A Yes.

BY MR. ROSENBLATT:

Q And have you continued to follow those patients over time?

MR. FAES: Objection.

A Many of those patients came back to me.

BY MR. ROSENBLATT:

Q And in the literature that you've reviewed as well as in your clinical experience, have you noticed any significant distinction -- any significant clinical distinction regarding mechanically cut versus laser cut?

MR. FAES: Objection.

A I have not sensed any difference in between.

BY MR. ROSENBLATT:

Q And if there was a difference, would you be more aware of any clinical impact it may have?

MR. FAES: Objection.

A Certainly.

BY MR. ROSENBLATT:

Q Are you aware of any clinical literature that has

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demonstrated that mechanically cut TVT is safer than laser cut TVT or that laser cut TVT is safer than mechanically cut TVT?

A I don't see any credible report which would say either one.

Q You were asked some questions about -- I think you were asked different versions of the question about how many revision procedures you've done or how many removal procedures you've done. But just so we are clear, do you do your best to track the complications that you treat?

MR. FAES: Objection.

A Definitely.

BY MR. ROSENBLATT:

Q And would that be true for nonmesh procedures and for mesh procedures?

MR. FAES: Objection.

A Everything I do, I want to see how good my outcomes are.

BY MR. ROSENBLATT:

Q And if you noticed a significant trend in treating complications from your incontinence procedures, would you -- or strike that.

Have you noticed any significant changes in treating complications from incontinence procedures?

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A If I noticed anything, I would definitely make a change in my practice.

Also, I forgot to tell that actually almost throughout my practice, I published my outcomes in one lit form or another. It must be sometimes retrospective review or future review. So I've been on top of my outcomes, and diligently, to be able -- I've presented them in meetings, and some turn into papers, abstracts and papers. So I know what my complication rates are very well.

Q And, Doctor, is there a difference in removing mesh versus just doing a simple urethrolysis or trimming some mesh from an exposure?

A There certainly is. I can tell you: I don't think there is any mesh complication, as we call it, in terms of either exposure or causing voiding problems, both of which require revision, or sometimes chronic pain, that I cannot take care of with a simple same-day procedure.

Q And I believe you told Mr. Faes that the exposure rate for midurethral slings like TVT and TVT-O were somewhere around 2 percent. Is that correct?

A Yes.

Q And what is that based on?

A So that, also, in line with my own personal

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experience, well tracked and reported, because we also publish our data. That is -- obviously, I don't -- I like to share my own data with my patients, but I really regard the numbers which come from these large randomized prospective trials.

And when the randomized trials get into a systematic review and the most formal methodology with the meta-analysis, the value of that is huge.

So Cochrane database, Schiff's report, Maher's report, Ford's report, Tomicelli's report -- these matter. And they all agree on one thing: That mesh erosion rate is about 2 percent. Revision for mesh is about 1 to 3 percent across the studies.

Q Doctor, I'm handing you what's been marked as Exhibit 18, which is the Ford 2015 Cochrane review. Do you see that?

A Right.

Q And is this one of these studies that you relied upon and cited in your report?

A Correct. And I just mentioned this as one of the highest regarded analyses, which covered all the studies up to that date.

Q And, Doctor, if you turn to the last page -- well, before we go there, is it correct that this Cochrane review tracked 81 randomized controlled trials

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that included approximately 12,113 women?
MR. FAES: Objection.
A That is correct.
BY MR. ROSENBLATT:
Q And why is it you would rely on something like a Cochrane review that's composed of 81 RCTs as opposed to just one study?
A Because they don't base their conclusions on case reports or animal studies. They have high standards.
They first grade the studies with respect to their quality, methodology. They don't include studies which have -- do not describe their definitions well, for example, and some of these things. And they have to have certain number of -- for the sample size, they have to have certain years of follow-up, and they have to have certain cutoffs for dropouts and patient wants to follow up.
When they did that, they were able to include some of the studies for comparison, and this came to be 81 trials.
Q And, Doctor, you were asked some questions about -- what was it? It was a question that I believe was referencing an older 2009 Cochrane review about the data being poor.
Do you recall that question?

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A Correct.
Q And counsel just referred to a Cochrane review citing the quality of data as being poor; he didn't tell you which systematic review he was referring to?
MR. FAES: Objection.
A I agree.
BY MR. ROSENBLATT:
Q And if you look on the last page of this publication under the paragraph starting "Adverse Effects" --
A Right.
Q -- and towards the bottom it says "There is moderate quality evidence that overall reported rates of tape-related complications are low, such as erosion of the tape into the vagina, at about 2 percent for both routes of tape insertion. The reported occurrence of problems with sexual intercourse, including pain, was low, and leakage of urine during intercourse are improved following insertion of these tapes."
Did I read that correctly?
A Yes.
Q And what did the 2015 Ford Cochrane review determine as far as the quality of evidence?
A Moderate quality.
Q And then the limitations of the review, do they

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again mention that most of the results are based on moderate quality evidence?
A Correct.
Q So would it be accurate as of this 2015 Cochrane review -- what counsel was asking -- that most of the data would be poor?
MR. FAES: Objection.
A That would be really wrong.
BY MR. ROSENBLATT:
Q And, Doctor, how would you describe the quality of evidence for the Burch colposuspension procedure and the autologous fascial sling?
A Poor.
Q Is there any procedure to treat stress urinary incontinence from a clinical data perspective that comes even close to being comparable to midurethral slings?
MR. FAES: Objection.
A I don't think there ever will be.
BY MR. ROSENBLATT:
Q Is that why you had a difficult time thinking, you know, what would be next in line as far as the best study and treatment?
MR. FAES: Objection.

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BY MR. ROSENBLATT:
A I can't imagine if there is anything.
I guess one thing would be really good is like if we had 17-year data for 2,000 patients, every single patient followed up. Something like that.
Q And are you aware of multiple 17-year follow-up studies for TVT?
MR. FAES: Objection.
A There are two of them now.
BY MR. ROSENBLATT:
Q And if there were three, you wouldn't -- that wouldn't surprise you?
MR. FAES: Objection.
A I wouldn't really be surprised, because, again, actually this is one thing we can track really well. That's another thing that actually -- midurethral sling lends itself to good follow-up.
BY MR. ROSENBLATT:
Q And turning to the -- so it would be the third page under "Author's Conclusions." It starts off by saying "Midurethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence, SUI, in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term

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and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI."

Did I read that correctly?

MR. FAES: Objection.

A I agree with every single sentence in there. I'm so happy that actually something like that comes from Cochrane Database, which is regarded highly because of their objectivity and the quality they are seeking for at all times.

BY MR. ROSENBLATT:

Q Did Mr. Faes show you any studies demonstrating that TVT or TVT-O degraded?

MR. FAES: Objection.

A No.

BY MR. ROSENBLATT:

Q Did Mr. Faes show you any clinical studies demonstrating that TVT or TVT-O frayed to the point of causing any clinical significance?

MR. FAES: Objection.

A No.

BY MR. ROSENBLATT:

Q Did Mr. Faes show you any clinical studies demonstrating any clinically significant difference

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comparing mechanically cut versus laser cut --

A No.

MR. FAES: Objection.

BY MR. ROSENBLATT:

Q -- TVT?

Doctor, Exhibit 8 was an invoice of $500. It looks like a consulting fee for the Ethicon Incontinence and Pelvic Floor Summit.

A Correct.

Q What was the purpose in attending that summit in 2011?

A I remember details, some details about it. That it was basically a gathering of opinion leaders in the area, in a place where we could all share our opinions on some changes they wanted to introduce. They were getting our input on their process and new R&D.

Q And was that a helpful thing?

A It really helped me a lot, because those meetings allow me to exchange experiences among my colleagues, and many of them do some things more than I do. And so, in my mind, that definitely improves my knowledge and...

Q So if you had stayed back in the operating room instead of getting this $500 flat fee, would you have made more with this $500 consulting fee?

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MR. FAES: Objection.

A I mean it's definitely symbolic compared to what we really could do professionally for that time spent there. But for me, that is still valuable because that is a great forum for me to exchange ideas.

BY MR. ROSENBLATT:

Q And when you said they had thought leaders, would they have included thought leaders of all different folks with differing opinions?

A That is correct.

At that time, I was not necessarily a heavy TVT or Prolift user, for example, but they included me there. And that didn't really change my attitude either. So prior to that and now, but I had not seen a meeting, and still the same; it does not change how I approach procedures.

Q Exhibit 9 was an email that looks like you wrote in 2009. One of the things that you wrote though was about TVT being back, and you said you were glad it's back.

A Correct.

Q Did counsel ask you about that portion of the email?

A No.

MR. FAES: Objection.

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BY MR. ROSENBLATT:

Q And is Yale currently stocking TVT?

A Correct.

Q And are you glad that Yale is stocking TVT?

A I'm extremely happy that we have it.

Q You were also shown the 2015 TVT IFU. Do you recall that?

A Yes.

Q And you were asked some questions starting with acute and/or chronic pain and various other complications that were added to the 2015 IFU, right?

A Correct.

Q Is acute and/or chronic pain a risk that can occur with any incontinence procedure?

MR. FAES: Objection.

A Yes.

BY MR. ROSENBLATT:

Q Is voiding dysfunction a potential complication that can occur with any incontinence procedure?

MR. FAES: Objection.

A Yes.

BY MR. ROSENBLATT:

Q Is pain with intercourse, which in some patients may not resolve, a potential complication of any incontinence procedures?

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MR. FAES: Objection.
A Correct.
BY MR. ROSENBLATT:
Q Would neuromuscular problems, including "acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area may occur," a potential complication of any incontinence procedure?
MR. FAES: Objection.
A Yes.
BY MR. ROSENBLATT:
Q Is recurrence of incontinence a potential complication of any incontinence procedure?
MR. FAES: Objection.
A Certainly.
BY MR. ROSENBLATT:
Q Is bleeding, including hemorrhage or hematoma, a potential complication of any incontinence procedure?
MR. FAES: Objection.
A Yes.
BY MR. ROSENBLATT:
Q Is "one or more revision surgeries may be necessary to treat these adverse reactions" a potential complication of any incontinence procedure?
MR. FAES: Objection.
A Correct.

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BY MR. ROSENBLATT:
Q Are all of those potential complications risks that you would expect residents and fellows to be familiar with?
MR. FAES: Objection.
A Absolutely.
BY MR. ROSENBLATT:
Q And would that be true for mesh or nonmesh surgeries?
MR. FAES: Objection.
A That is very true.
BY MR. ROSENBLATT:
Q And was that true even before TVT was available in 1998?
MR. FAES: Objection.
A It's always true in any area of medicine, that we -- those are potential complications of any type of procedure.
BY MR. ROSENBLATT:
Q And then plaintiffs' counsel showed you a Desara IFU, or I'm not sure where he got it from. But do you recall seeing that?
A Yes.
Q Do you use Desara's midurethral slings?
A Not currently.

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Q And have you noticed any clinical significance of mesh fraying?
MR. FAES: Objection.
A I haven't.
BY MR. ROSENBLATT:
Q Okay. You were also shown on Exhibit 14 a photograph of mesh here. You don't know how this mesh was used or whether or not this was a demo unit that had just been improperly stretched, do you?
MR. FAES: Objection.
A Correct.
BY MR. ROSENBLATT:
Q Okay. You were asked some questions about the ProtoGen device?
A Yes.
Q You are aware that that's not a polypropylene midurethral sling, right?
A No, not at all.
Q You were asked about a hypothetical study that showed a 19 percent erosion rate.
MR. FAES: Object to form.
BY MR. ROSENBLATT:
Q Do you recall that?
A Yes.
Q And I believe you said that you wouldn't quote

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your patient a 19 percent rate or a 0 percent rate, even though there may be studies to support either.
Could you just explain that in a little more detail.
MR. FAES: Objection.
A Correct. I cannot imagine there would be any procedure or any surgeon who could have zero complication. So that is not believable.
Same as either I can't imagine how a capable skilled surgeon can have 19 percent TVT exposure rate.
BY MR. ROSENBLATT:
Q And what are some of the factors or risk factors that can contribute to complications of any surgery?
A There are patient variables which definitely affect our results.
Q Such as?
A You know, patient being heavy, patient having previous surgeries or concomitant surgeries, having a hysterectomy at the same time, their having diabetes, and patient probably not complying with postoperative instructions. All of these are factors which are not within my control.
Q What about surgeon volume or surgeon experience?
A I think that is the most important component in any of these. I agree with you saying that someone who

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does five of these in one year will not be even close to someone who is doing couple hundred a year. Obviously the complication rates will be different.

So surgeon's volume, experience, and skills are the key. That's why we always want to seek out the best surgeons in the area.

Q Then you were asked some questions about IFU, and specifically the Faber study, which I believe showed that around 37 percent of surgeons had never even reviewed the IFU for midurethral sling.

In your opinion, is there a difference between even reviewing the IFU as opposed to relying upon an IFU?

A That's a great one too. Yes, exactly. So I don't think any physician relies on it. And reviewing is one thing and relying on it is another thing.

Q Have you in fact reviewed the IFUs prior to this litigation for the TVT products?

A I definitely did.

Q And did you rely on the IFUs?

A No. It has not changed what I have been doing for years in my consent process.

Q And although you, I believe, said you had not done a survey or a formal analysis of what surgeons know at any given time, would your review of the peer

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reviewed medical literature, your experience on various editorial boards, your experience on various educational systematic review groups, as well as your experience in teaching residents and fellows, inform you as to what surgeons know --

MR. FAES: Objection.

BY MR. ROSENBLATT:

Q -- or are expected to know?

A Right.

Q So you may not have necessarily done a SurveyMonkey survey, but you would have that knowledge from your experience?

MR. FAES: Objection.

A It is definitely clear -- my observations, my discussions, debates. And every meeting we get together, we just basically follow up on what we do. And I agree with you on that.

BY MR. ROSENBLATT:

Q You were asked some questions about shrinkage or contraction just in general, and then whether or not shrinkage and contraction occur -- of the TVT mesh occurs. How would you distinguish the two?

MR. FAES: Objection.

A So contracture or shrinkage will occur with your native tissue repair too. And there are many variables

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which affects that. And if it ever happens to a significant level with a TVT, it could be disastrous really. It would definitely show up on all of these studies.

BY MR. ROSENBLATT:

Q And have you in fact reviewed ultrasound studies demonstrating no shrinkage or contraction of the TVT?

MR. FAES: Objection.

A Right. There are two studies at least, that I know of, that really showed clearly that it does not exist.

BY MR. ROSENBLATT:

Q What methodology did they use to determine that shrinkage or contraction of a TVT didn't exist?

A So they use an ultrasound.

Q Doctor, you were asked some questions about -- just going back to midurethral slings being the most extensively studied in terms of quality and quantity. You recall those questions?

A Yes.

Q In all of these studies that you are aware of, the randomized control trials, in addition to evaluating efficacy or whether or not the procedure works, are those studies also evaluating safety by tracking complications that are reported?

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A Definitely.

Q Would a Prolene -- if a Prolene suture had an IFU, would it tell you as a pelvic floor surgeon how to perform a sacrospinous ligament fixation?

A Not at all.

Q Would a Prolene suture IFU tell you how to perform a uterosacral ligament suspension?

A That would be funny.

Q So I believe you told plaintiffs' counsel that the Burch procedure and the autologous fascial sling procedure, they are not medical devices, right?

A They are not.

Q So if they were to suggest that those two procedures are alternative designs, would that be correct or incorrect?

MR. FAES: Objection.

A Those are alternative surgeries to midurethral sling procedures.

BY MR. ROSENBLATT:

Q But they are not devices, correct?

MR. FAES: Objection.

A They are not devices.

BY MR. ROSENBLATT:

Q Are you aware of any synthetic midurethral sling on the market today that has a larger pore size than

the TVT mesh?
A I am not.
Q You were asked some questions about a mesh potentially being too stiff. Do you recall that?
A Correct.
Q What would happen, in your opinion, if a mesh was potentially too flimsy or if the pores were too large?
A It would probably fail.
Q And have there been any randomized control studies evaluating a larger pore, lighter weight mesh for stress urinary incontinence specifically evaluating that hypothetical device against the gold standard TVT?
A No.
Q If plaintiffs' experts were going to suggest that such a device would hypothetically be safer, would you expect them to at least be able to cite you and rely on Level I data for that?
MR. FAES: Objection.
A Correct. So it requires substantiation, and I'm not sure if that ever exists or will ever happen.
MR. ROSENBLATT: I think that's all I have for you, Doctor. Thank you for your time.
THE WITNESS: Thank you.
(Discussion off the record.)

THE STENOGRAPHER: I'm going to ask you to confirm your billing and copies on the record.
MR. ROSENBLATT: Yes, please. I want a rough and an e-tran, yes.
THE STENOGRAPHER: And, Attorney Faes, you want the original and e-tran and an expedited copy due Monday?
MR. FAES: I don't think I need an original. I don't need paper copies at all.
THE STENOGRAPHER: The rest of what I said is true though?
MR. FAES: Yes. I do need it expedited, unfortunately.
(Deposition concluded: 8:07 p.m.)

ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
[WITNESS NAME] DATE

Subscribed and sworn to
before me on this _____day
of_____,20___, by _____
_____,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____

CERTIFICATE

I hereby certify that I am a Notary Public in and for the State of Connecticut duly commissioned and qualified to administer oaths.

I further certify that the deponent named in the foregoing deposition was by me duly sworn and thereupon testified as appears in the foregoing deposition; that said deposition was taken by me stenographically in the presence of counsel and transcribed by means of computer-aided transcription by the undersigned, and the foregoing is a true and accurate transcript of the testimony.

I further certify that I am neither of counsel nor attorney to either of the parties to said suit, nor of either counsel in said suit, nor related to or employed by any of the parties or counsel to said suit, nor am I interested in the outcome of said cause.

Witness my hand and seal as Notary Public this 8th of October, 2018.

Vicki S. McManus
NOTARY PUBLIC

My commission expires: July 2021
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